RECORD AND BRIEFS.

No. 16-712

FILED
OCT 26 2017
OFFICE OF THE CLERK

In The

# Supreme Court of the United States

OIL STATES ENERGY SERVICES, LLC,

*Petitioner,*

v.

GREENE'S ENERGY GROUP, LLC, et al.,

*Respondents.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## BRIEF OF *AMICUS CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL IN SUPPORT OF RESPONDENTS

ANDREW S. GOLDMAN
*Counsel of Record*
KNOWLEDGE ECOLOGY INTERNATIONAL
1621 Connecticut Avenue NW, Suite 500
Washington, D.C. 20009
(202) 332-2670
andrew.goldman@keionline.org

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

## QUESTION PRESENTED

Whether *inter partes* review – an adversarial process used by the Patent and Trademark Office ("PTO") to analyze the validity of existing patents – violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.

TABLE OF CONTENTS

Page

Question Presented ..... i

Table of Contents ..... ii

Table of Authorities ..... iv

Interest of *Amicus Curiae* ..... 1

Summary of Argument ..... 1

Argument ..... 3

I. The *Inter Partes* Review System Is Only One of the USPTO's Congressionally-Delegated Administrative Responsibilities, and Is an Important Corrective Mechanism ..... 3

A. There are a Significant Number of Errors Made in the Grants of Patents Requiring Certificates of Correction ..... 4

B. The *Inter Partes* Review Plays an Important Role in Clearing Patent Thickets ..... 7

C. The USPTO Patent Term Extension Process is Another Congressionally-Enabled Administrative Process Endorsed by Some of the Same Parties that Complain About *Inter Partes* Review ..... 10

II. Patents Are Not the Only Way to Induce Innovation and Should Not Be Treated As Such ..... 11

TABLE OF CONTENTS – Continued

Page

A. The World Intellectual Property Organization's Global Innovation Index Describes Eighty Variables Factoring Into Innovation, With Only Four Relating to Patents Granted ..... 12

B. There are Numerous Non-Patent Mechanisms to Induce Investments in Innovation in the United States ..... 13

1. The Orphan Drug Act Provides Seven Years of Market Exclusivity for Drugs for Rare Diseases ..... 14

2. Other Laws Create *Sui Generis* Exclusive Marketing Rights and Rights in Test Data ..... 15

C. The Interest in Delinkage Proposals for Alternative Systems of Innovation for Medical Technologies Has Grown as Problems of Access and Affordability Have Worsened ..... 16

Conclusion ..... 19

# TABLE OF AUTHORITIES

Page

CASES:

*Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576 (2013) ..... 7

*Bowman v. Monsanto*, 596 U.S. 278 (2013) ..... 16, 17

STATUTES:

7 U.S.C. § 136a ..... 16

21 U.S.C. § 355(c)(3)(E)(ii) ..... 15

21 U.S.C. § 355(c)(3)(E)(iii-iv) ..... 15

21 U.S.C. § 355(j)(5)(F)(ii) ..... 15

21 U.S.C. § 355(j)(5)(F)(iii-iv) ..... 15

21 U.S.C. § 355a ..... 16

26 U.S.C. § 45C ..... 14

35 U.S.C. § 156 ..... 10

35 U.S.C. § 156(d)(2)(B) ..... 11

35 U.S.C. § 254 ..... 5

35 U.S.C. § 255 ..... 5

42 U.S.C. § 262(k)(7)(A) ..... 16

PUBLIC LAWS:

Pub. L. No. 97-414, Jan. 4, 1983, 96 Stat. 2049 ..... 14

TABLE OF AUTHORITIES – Continued

Page

REGULATIONS:

21 C.F.R. 314.108 ..... 15

21 C.F.R. 316.31 ..... 14

OTHER AUTHORITIES:

Biotechnology Innovation Organization Press Release, *Biotech Gets Big Boost From Bills Enacted by Congress* (Nov. 22, 1999) ..... 11

Brief of Eagle Forum Education & Legal Defense Fund as Amicus Curiae in Support of Petitioner, *Oil States* (Aug. 30, 2017) ..... 5

Brief of Intellectual Property Owners Association as Amicus Curiae in Support of Neither Party, *Oil States* (Aug. 31, 2017) ..... 4

Brief of Knowledge Ecology International as Amicus Curiae in Support of Petitioner, *Bowman v. Monsanto*, 596 U.S. 278 (2013) ..... 17

Brief of Security People, Inc. as Amicus Curiae in Support of Petitioner, *Oil States* (Aug. 29, 2017) ..... 5

Brief of US Inventor, Inc. *et al.* as Amici Curiae in Support of Petitioner, *Oil States* (Aug. 29, 2017) ..... 5

Jorge L. Contreras and Jacob S. Sherkow, *CRISPR, surrogate licensing, and scientific discovery*, Science, Vol. 355, Issue 6326 (Feb. 2017) ..... 8

TABLE OF AUTHORITIES – Continued

Page

Convention Establishing the World Intellectual Property Organization, Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979 (1967) ..... 12

Cornell University, INSEAD, and WIPO, *The Global Innovation Index 2017: Innovation Feeding the World* (2017) ..... 12, 13

H.R. 1776, 115th Congress (2017) ..... 18

Juno Therapeutics, Annual Report for Fiscal Year 2016, Form 10-K (Filed Mar. 1, 2017) ..... 9

Aaron S. Kesselheim, *et al.*, *Gene Patenting – The Supreme Court Finally Speaks*, N Engl J Med (Aug. 29, 2013) ..... 7

James Love, *Alternatives to the Patent System that are Used to Support R&D Efforts, Including Both Push and Pull Mechanisms, With a Special Focus on Innovation-Inducement Prizes and Open Source Development Models*, World Intellectual Property Organization, CDIP/14/INF/12 (Sept. 19, 2014) ..... 13

James Love, *Errors in Patent Grants, More Common in Medical Patents*, Bill of Health, Harvard Law Petrie-Flom Center (Oct. 21, 2017) ..... 6

James Love, *Orphan Drugs Designations and Approvals have Something to Say about Risks*, Bill of Health, Harvard Law Petrie-Flom Center (Sept. 25, 2017) ..... 14

TABLE OF AUTHORITIES – Continued

Page

David C. Mowery, *Breakthrough innovations in aircraft and the intellectual property system, 1900-1975*, Economic Research Working Paper No. 25, World Intellectual Property Organization (Nov. 2015) ..... 7

Petition for a Writ of Certiorari, *Oil States Energy Services, Inc. v. Greene's Energy Group, LLC*, No. 16-712 (Nov. 23, 2016) ..... 4

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, *Recommendations for Incentivizing the Development of Therapeutics, Diagnostics, and Vaccines to Combat Antibiotic-Resistance*, Working Group Draft (Sept. 2017) ..... 17

S. 771, 115th Congress (2017) ..... 18

The Secretary-General, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Medicine* (Sept. 2016) ..... 17

## INTEREST OF *AMICUS CURIAE*[1]

Knowledge Ecology International ("KEI") is an international non-profit, non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. In particular, KEI is focused on the management of these resources in the context of social justice. KEI is drawn to areas where current business models and practices by businesses, governments or other actors fail to adequately address social needs or where there are opportunities for substantial improvements. KEI has expertise on issues pertaining to intellectual property and medical technologies, among other fields.

KEI's interest in the present case stems from its belief that there is significant public interest in the *inter partes* review system as an important check against the incorrect grant of patents.

## SUMMARY OF ARGUMENT

We think it is abundantly clear that patents are public rights derived from an extensive federal regulatory scheme, and that the *inter partes* review mechanism was created through a proper exercise of

[1] Pursuant to Supreme Court Rule 37.3(a), the parties have consented to the filing of this brief. Pursuant to Supreme Court Rule 37.6, no counsel representing any party to the case authored this brief, in whole or in part, and no person or entity other than *amici* or its counsel made any monetary contribution to the preparation or submission of this brief.

congressional authority. Therefore, we do not wish to take the Court's time in iterating arguments well made in numerous briefs already before the Court, including those of Respondent Greene's Energy Group, LLC, the opposition to the petition for a writ of certiorari by the Federal Respondent, and briefs of other *amici curiae* such as the American Intellectual Property Law Association with regard to the question of Article III constitutionality. The Court has rejected cert on exactly the same question as this case before it three times in recent years, and we join with those who express befuddlement as to why this case should be different.

We instead wish to offer comment on the argument repeated by Petitioner as well as numerous *amici* in support of Petitioner that the patent system is weakened by the United States Patent and Trademark Office ("USPTO") having an administrative review that can be used to narrow or eliminate patent claims that were originally granted because of errors by the USPTO or applicant, and that by narrowing or eliminating claims innovation is harmed and national wealth reduced.

1. We note, as others have, the negative consequences of granting patents that do not meet inventive step or which are not novel, and provide evidence regarding patent corrections as evidence of the need for corrective mechanisms such as the *inter partes* review. We note the number of corrections to patent applications is higher for certain medical fields than for patents in general. We also discuss the administrative

process to extend patent terms that some of the vocal opponents to *inter partes* review have enthusiastically endorsed.

2. We also note that while the patent system often plays a positive role in inducing investments in innovation, it by no means is the only instrument used to do so. We discuss some of the non-patent mechanisms already available for the development of medical technologies, as well as important policy proposals for non-patent "delinkage" models currently being debated as alternatives to a patent model that leads to high prices and problems of access both in the United States and abroad.

It would be not only an error of law to rule in favor of Petitioner but would also be an error of significant policy consequence to lay such deference at the feet of the patent system at a moment when there are critical decisions to be made with regard to the role patents play or do not play in the innovation of new medicines.

## ARGUMENT

### I. The *Inter Partes* Review System Is Only One of the USPTO's Congressionally-Delegated Administrative Responsibilities, and Is an Important Corrective Mechanism

Mistakes in the patent process are routinely made, and the *inter partes* review plays an important role as a corrective mechanism. Furthermore, we note other USPTO administrative processes bearing upon the

rights of patent holders, including for patent term extension.

### A. There are a Significant Number of Errors Made in the Grants of Patents Requiring Certificates of Correction

Several parties filing briefs in this case have overstated the importance of the patent system in promoting innovation, and argued incorrectly that the absence of a patent will leave policy makers without the possibility of mechanisms to induce investment, thus encouraging the court to facilitate the granting of monopolies even where an application has failed to demonstrate novelty or inventive step. *See* Petition for a Writ of Certiorari at p. 33, *Oil States Energy Services, Inc. v. Greene's Energy Group, LLC*, No. 16-712 (Nov. 23, 2016) ("According to one estimate, *inter partes* review has, thus far, destroyed $546 billion of the United States economy by invalidating patents, and wiped out about $1 trillion in value by devaluing the companies holding those patents. Even worse, that number is likely underestimated since '[i]t does not include lost opportunities, disincentives to innovation, the inability to raise money due to the decrease in collateral, and the loss of jobs without those investments.'") (citation omitted); *see also* Brief of Intellectual Property Owners Association as Amicus Curiae in Support of Neither Party at p. 2, *Oil States* (Aug. 31, 2017) ("A characterization of patents as public rights by this Court could diminish the value of patents, and reduce the flow of investment essential to making the future innovations

needed to power America's technology-driven economy."); Brief of US Inventor, Inc. *et al.* as Amici Curiae in Support of Petitioner at p. 18, *Oil States* (Aug. 29, 2017) ("With the PTAB, Congress and the Executive Branch diminish the rewards inventors have come to expect from inventing and patenting. This has had a negative effect of depriving rights holders of their investment-backed expectations."); Brief of Security People, Inc. as Amicus Curiae in Support of Petitioner at pp. 2-3, *Oil States* (Aug. 29, 2017) ("The *inter partes* review process, as constituted, has an absolutely destabilizing effect on long-term patent innovations and development, and the remuneration for such efforts. And, as such, is profoundly detrimental to the well-being and purpose of fostering patents as envisioned by the U.S. Constitution."); Brief of Eagle Forum Education & Legal Defense Fund as Amicus Curiae in Support of Petitioner at p. 4, *Oil States* (Aug. 30, 2017) ("The AIA has created havoc for the patent framework that had worked remarkably well for two and-a-quarter centuries. The traditional patent system, prior to the AIA, played an essential role in incentivizing the innovation that brought productivity and wealth to the American people far greater than anything ever seen in human history. Just as small businesses create most jobs, individual inventors have been responsible for most innovation.").

One measure of the mistakes that are made when patents are granted is the corrections to the patents that are recorded after the original patent has been granted. Pursuant to 35 U.S.C. § 254 and § 255, errors

by the Patent Office itself or by the applicant can be addressed through the issuance of a certificate of correction. Between January 1, 2010, and December 31, 2015, 3,551,058 patents were granted by USPTO. Of these, 392,557, or 11.1%, were later issued certificates of correction, indicating mistakes made on the original patent.[2]

There is a distinct difference in the percentage of patents that received certificates of correction by the subject matter. In particular, patents with medical subject matter had much higher rates of correction. For example, for the same time period, consider the rate of corrections issued for patents that were identified with the following search terms: cancer: 21.2%; diabetes: 22.3%; HIV: 24%; asthma: 23.1%; multiple sclerosis: 24.1%; Alzheimer's: 22.6%; pharmaceutical composition: 23.2%; Antibody-drug conjugates: 26.9%. James Love, *Errors in Patent Grants, More Common in Medical Patents*, Bill of Health, Harvard Law Petrie-Flom Center (Oct. 21, 2017), *available at* http://blogs.harvard.edu/billofhealth/2017/10/21/errors-in-patent-grants-more-common-in-medical-patents/.

Compare the rate of correction to patents with a medical subject matter to patents with other search terms, such as: bicycle: 9.5%; engine: 11%; missile:

---

[2] This search was based upon the following query to the USPTO online database of patents, on October 19, 2017 (isd/20000101->20151231), for all patents, and (isd/20000101->20151231 AND cofc/yes) for patents with a certificate of correction issued.

11.8%; can opener: 8.3%; coffee maker: 6.9%; battery: 11.6%; photovoltaic: 12.1%; wind turbine: 9.1%. *Id.*

### B. The *Inter Partes* Review Plays an Important Role in Clearing Patent Thickets

The notion that the gain of income for holders of low quality patents is an unambiguous benefit of the patent system purposely ignores the cost of the monopoly to the general public. When a patent is invalidated for not meeting statutory standards for inventive step, one person's billion dollar loss is the public's billion dollar savings. Moreover, overly broad patents or patents on trivial, obvious or non-novel innovations can block innovation by others. Patent thickets were a major barrier to the development of commercial airlines, and innovation flourished after the federal government took steps to curb the exclusive rights associated with patents, by forcing patent holders to license non-exclusively on reasonable terms. David C. Mowery, *Breakthrough innovations in aircraft and the intellectual property system, 1900-1975*, Economic Research Working Paper No. 25, World Intellectual Property Organization (Nov. 2015), *available at* http://www.wipo.int/edocs/pubdocs/en/wipo_pub_econstat_wp_25.pdf.

The Court's decision in *Association for Molecular Pathology v. Myriad Genetics* created space for competition among suppliers and lowered prices for diagnostic tests for the BRAC1 gene. 569 U.S. 576 (2013); *see* Aaron S. Kesselheim, *et al.*, *Gene Patenting – The Supreme Court Finally Speaks*, N Engl J Med (Aug. 29,

2013), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMhle1308199. The precedent also encouraged drug companies to accelerate innovation for new drugs in other areas where broad patents had deterred innovation, including, for example, the development of new drugs for the hepatitis C virus, an area of therapy that had been plagued with litigation and restrictive licensing of overly broad patents.

The new CRISPR gene editing tools present major challenges for drug developments, because there are many patents that have overlapping and sometimes conflicting claims. Jorge L. Contreras and Jacob S. Sherkow, *CRISPR, surrogate licensing, and scientific discovery*, Science Vol. 355, Issue 6326, pp. 698-700 (Feb. 2017).

Likewise, the new chimeric antigen receptor T cell based therapies ("CAR T") have given rise to an acceleration of filings of patents. Patents mentioning the keywords "chimeric antigen receptor" as of October 24, 2017 included 29 patents granted to the University of Pennsylvania, a U.S. educational institution with a commercial licensing agreement with Novartis, a Swiss drug manufacturer.

Juno Therapeutics, an institution created by the Fred Hutchinson Cancer Treatment Center, Memorial Sloan Kettering Cancer Center and Seattle Children's Research Institute, and which is involved in considerable litigation over its CAR T patents, describes its patent portfolio in its annual report: "As of December 31, 2016, our owned and licensed patent portfolio

consists of approximately 31 licensed U.S. issued patents, approximately 37 licensed U.S. pending patent applications, approximately 41 owned U.S. issued patents, and approximately 48 owned U.S. pending patent applications covering certain of our proprietary technology, inventions, and improvements and our most advanced product candidates. . . ." Juno Therapeutics, Annual Report for Fiscal Year 2016, Form 10-K, pp. 25-26 (Filed Mar. 1, 2017), *available at* https://www.sec.gov/Archives/edgar/data/1594864/000159486417000009/juno-123116x10k.htm. The Juno patent portfolio as described has included claims in thirteen different layers of technology. Juno noted it intends "to pursue, when possible, composition, method of use, dosing and formulation patent protection" and "may also pursue patent protection with respect to manufacturing and drug development processes and technology." *Id.* at p. 26.

Bellicum, Bluebird Bio, Celgene, Cellectis, Chimera Bioengineering, Editas Medicine, Juno, Kite Pharma/ Gilead, Miltenyi, Pfizer, St. Jude's Children's Hospital, the City of Hope, the University of Pennsylvania/ Novartis group, Ziopharm, and many other businesses and research institutions have filed for patents on CAR T related technologies. The challenge for development of this potentially revolutionary technology to treat cancer is not the lack of patents, but rather the complex, overlapping and layered patent claims which reduce the freedom to operate for businesses. Here the *inter partes* review process will play an important role in reducing the number of low quality

patents that involve patent claims that are not novel or involve trivial or obvious innovations. Simply put, more is not always better when it comes to patents.

The *inter partes* review process can eliminate patents and patent claims when parties cannot demonstrate an innovation is novel or nonobvious. The decision to invalidate a bad patent or bad patent claim on a timely basis and at a reasonable cost to the parties enables others the benefit of the freedom to innovate and makes it easier for these competitors to raise capital to invest in products, including products based upon truly novel and inventive technologies.

To the extent that the patent system is used to protect investments without invention, which appears to be the desire of some of the opponents of the *inter partes* review system, there are other more appropriate policy tools which are available.

### C. The USPTO Patent Term Extension Process is Another Congressionally-Enabled Administrative Process Endorsed by Some of the Same Parties that Complain About *Inter Partes* Review

The *inter partes* review mechanism is one of a number of administrative functions that USPTO is tasked with that bears on the rights of the patent holder. Among these include, for example, the ability for the USPTO to grant patent term extensions. 35 U.S.C. § 156. Subject to certain statutory requirements, the patent holder or its agent can submit an

application to the USPTO within sixty days of the product's first approval for commercial marketing or use to have the patent term extended by the time equal to the regulatory review period, minus reductions for periods of time where the applicant did not act with due diligence during that regulatory review period. *Id.* The statute permits any person to submit a petition within 180 days of the publication of a regulatory review period challenging the determination of due diligence, and has the right to request an informal hearing on the matter. 35 U.S.C. § 156(d)(2)(B).

Some parties opposing the *inter partes* review system that can limit patent rights are among the vocal proponents of using this administrative process to extend patent terms. Biotechnology Innovation Organization Press Release, *Biotech Gets Big Boost From Bills Enacted by Congress* (Nov. 22, 1999), *available at* https://www.bio.org/media/press-release/biotech-gets-big-boost-bills-enacted-congress.

## II. Patents Are Not the Only Way to Induce Innovation and Should Not Be Treated As Such

The notion that bad patents make good policy is short sighted, and calls upon the Court to rely too much on the patent system, as if other mechanisms outside of the patent system did not exist. We discuss a few examples among the plethora of mechanisms to subsidize and reward investments in innovation that do not rely upon patents granted for inventions,

particularly in the context of medical technologies. These examples put the lie to the statements of Petitioner and some of the *amicus curiae* who would lead the Court to believe that patents are the beginning and end of what is in fact a much more complex system of innovation. We additionally discuss some of the proposals for delinkage models that seek to sever the link between innovation and high prices.

### A. The World Intellectual Property Organization's Global Innovation Index Describes Eighty Variables Factoring Into Innovation, With Only Four Relating to Patents Granted

The World Intellectual Property Organization ("WIPO") is a specialized agency of the United Nations, created "to promote the protection of intellectual property throughout the world." Convention Establishing the World Intellectual Property Organization, Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979, Art. 3, *available at* http://www.wipo.int/treaties/en/convention/.

Every year since 2007, WIPO has published a Global Innovation Index ("GII"). The GII uses many variables to measure and rank the innovation performance of countries around the world. The purpose of the GII is to "find metrics and approaches that better capture the richness of innovation in society. . . ." Cornell University, INSEAD, and WIPO, *The Global Innovation Index 2017: Innovation Feeding the World*

(2017), *available at* http://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2017.pdf.

In the *Global Innovation Index 2017*, WIPO ranks the United States fourth in the world, but it is notable how few patent variables factor into that equation. *Id.* at p. 306. The GII has eighty variables, organized into seven clusters, and only four of the variables relate to the number of patents granted. *Id.* Among the factors that are highlighted are political and institutional stability, the quality of infrastructure, spending on education, the ease of starting a business, getting credit and resolving insolvency, the cost of redundancy dismissal, and many others that far outnumber patent grants, and this for an institution that is primarily funded by fees to file patents under the Patent Cooperation Treaty. *Id.*

### B. There are Numerous Non-Patent Mechanisms to Induce Investments in Innovation in the United States

In the United States, there are a variety of non-patent mechanisms that provide monopoly rights as an incentive to innovation. James Love, *Alternatives to the Patent System that are Used to Support R&D Efforts, Including Both Push and Pull Mechanisms, With a Special Focus on Innovation-Inducement Prizes and Open Source Development Models*, World Intellectual Property Organization, CDIP/14/INF/12 (Sept. 19, 2014), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_14/cdip_14_inf_12.pdf.

### 1. The Orphan Drug Act Provides Seven Years of Market Exclusivity for Drugs for Rare Diseases

The Orphan Drug Act, for example, provides market exclusivity for drugs designated as "orphan drugs", barring the Food and Drug Administration from approving any other application for the same drug or condition for a period of seven years. Pub. L. No. 97-414, Jan. 4, 1983, 96 Stat. 2049; *see also* 21 C.F.R. 316.31. Orphan drugs are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the United States, or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. *Id.* The law was expressly designed to address the problems of developing treatments for diseases where the small number of affected individuals may yield "relatively small sales in comparison to the cost of developing the drug" and be a complete disincentive to developing new drugs without additional financial incentives. *Id.* The law additionally provides for a fifty percent tax credit for qualifying clinical trials related to the development of an orphan drug. 26 U.S.C. § 45C.

Since the Orphan Drug Act came into effect in 1983, through September 17, 2017, the FDA has granted 4,350 orphan designations. From 2010 to 2016, seventy-five percent of all novel cancer drugs approved in the United States qualified as orphan products. James Love, *Orphan Drugs Designations and Approvals have Something to Say about Risks*,

Bill of Health, Harvard Law Petrie-Flom Center (Sept. 25, 2017), *available at* http://blogs.harvard.edu/billofhealth/2017/09/25/orphan-drugs-designations-and-approvals-have-something-to-say-about-risks/.

Both the orphan drug exclusivity and the orphan drug tax credit benefit drug developers regardless of the patent status of products.

### 2. Other Laws Create *Sui Generis* Exclusive Marketing Rights and Rights in Test Data

Several other laws create *sui generis* non-patent market exclusivity including exclusivities for new drugs, and for drugs where there has been a new clinical investigation. Under 21 U.S.C. § 355(c)(3)(E)(ii) and § 355(j)(5)(F)(ii), new drugs are granted a five year period of exclusivity during which time the FDA may not grant marketing approval to another drug under an abbreviated new drug application ("ANDA") or a 505(b)(2) application. *See also* 21 C.F.R. 314.108. Similarly, in instances where the FDA grants market approval for an already-approved drug, the application of which contains evidence of a new clinical investigation, the FDA is barred from granting marketing approval for an ANDA or 505(b)(2) application for another drug for a period of three years. 21 U.S.C. § 355(c)(3)(E)(iii-iv) and § 355(j)(5)(F)(iii-iv).

As part of the Affordable Care Act, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") guarantees biologic drugs a period of market exclusivity

of twelve years during which time the FDA may not approve a biosimilar application. 42 U.S.C. § 62(k)(7)(A).

There is a similar mechanism to create a hybrid system of exclusive and remuneration rights for test data used to register insecticides and pesticides. 7 U.S.C. § 136a.

A separate section of the Food Drug and Cosmetic Act creates a six-month period of exclusivity in exchange for conducting and submitting pediatric studies on the active moiety in response to a written request from the FDA. 21 U.S.C. § 355a.

The various exclusive rights in test data and the pediatric testing incentive are designed to induce investments in drug and chemical developments even when patents are not granted, and illustrate that policy makers do not have to rely inappropriately upon the patent system and the grant of bad patents to protect investments in drug development.

### C. The Interest in Delinkage Proposals for Alternative Systems of Innovation for Medical Technologies Has Grown as Problems of Access and Affordability Have Worsened

As KEI noted in its brief of *amicus curiae* in *Bowman v. Monsanto*, there is significant interest from academics, legislators, civil society, and other important stakeholders in developing alternative systems for innovation not dependent on a foundation

of exclusive rights in patents or *sui generis* rights. Brief of Knowledge Ecology International as Amicus Curiae in Support of Petitioner at pp. 20-25, *Bowman v. Monsanto*, 596 U.S. 278 (2013). Since that time, while drug prices both in the U.S. and abroad have continued to increase and worsen problems of access and affordability, the interest in delinkage has grown.

In September 2016, the United Nations Secretary-General's High-Level Panel on Access for Medicines issued a report calling upon countries to implement a new mechanism to fund R&D that delinks R&D costs from the prices of end products. The Secretary-General, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Medicine*, p. 8 (Sept. 2016), *available at* http://www.unsgaccessmeds.org/resources-documents/2017/7/19/report-of-the-united-nations-secretary-generals-high-level-panel-on-access-to-medicines.

On September 14, 2017, the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria unanimously endorsed a report that included a recommendation for "adoption of some form of a delinkage model as a pull incentive," which it described as "a proposed model to incentivize the development of new drug products in which profitability is separated from sales volume." Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, *Recommendations for Incentivizing the Development of Therapeutics, Diagnostics, and Vaccines to Combat Antibiotic-Resistance*, Working Group Draft (Sept.

2017), *available at* https://www.hhs.gov/sites/default/files/draft-incentives-report-september-2017.pdf.

In May 2017, the "Improving Access to Affordable Prescription Drugs Act" was proposed in the Senate and House of Representatives and called upon the Director of the National Institutes of Health to "enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study to examine . . . models of different possible means of delinking research and development costs from drug prices, including the replacement of the monopoly on new products as an incentive, with innovation inducement prize funds and push financing mechanisms as new incentives to stimulate the development of drugs, including drugs to treat bacterial infections, rare diseases, HIV/AIDS, and cancer." S. 771, 115th Congress (2017); H.R. 1776, 115th Congress (2017).

## CONCLUSION

For the reasons stated above, this Court should confirm the Constitutionality of the *inter partes* review process.

Respectfully submitted,

ANDREW S. GOLDMAN
*Counsel of Record*
KNOWLEDGE ECOLOGY INTERNATIONAL
1621 Connecticut Avenue NW, Suite 500
Washington, D.C. 20009
(202) 332-2670
andrew.goldman@keionline.org

October 26, 2017